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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,657	03/20/2001	Margaret Ann Johns	5947-01-DRK	4802

7590

07/29/2003

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/287,657

Applicant(s)

Johns et al.

Examiner

Stephen Buckler

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/17/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-34 is/are pending in the application.
- Of the above claim(s) 8-14, 17-20, & 22-34 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-2, 4, 6-7, 15-16, & 21 is/are rejected.
- ☒ Claim(s) 3 & 5 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner. — NEED ABSTRACT
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Part III DETAILED ACTION

1. Applicant's election of Group I without traverse, claims 1-7, 15-16, and 21, drawn to polynucleotides and first method of use, and SEQ ID NO:3, in Paper No. 7, filed 12/17/02, is acknowledged.
2. Claims 8-14, 17-20 and 22-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-2, 4, 6-7, 15-16, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA sequence encoding a polypeptide which is a voltage activated calcium channel (VSCC) $\alpha 2\delta$ -C subunit comprising SEQ ID NO:3, or an isolated DNA sequence encoding a polypeptide which is a voltage activated calcium channel (VSCC) $\alpha 2\delta$ -C subunit that hybridizes to SEQ ID NO:3 on a filter support at 65°C in 7% SDS and 0.125M sodium phosphate, followed by washing in 1% SDS, 20 mM phosphate buffer and 1 mM EDTA at 65°C for between about 30 minutes to 4 hours, or an

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isolated DNA sequence encoding a polypeptide which is a voltage activated calcium channel (VSCC) $\alpha 2\delta$ -C subunit that has at least 70% sequence identity to SEQ ID NO:3, does not reasonably provide enablement for isolated DNAs that hybridize to or share sequence identity with SEQ ID NO:3 that do not encode a voltage activated calcium channel (VSCC) $\alpha 2\delta$ -C subunit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not adequately describe or provide sufficient guidance or examples for DNAs that do not encode VSCC $\alpha 2\delta$ -C subunit proteins. The unpredictability in the molecular biological protein art is high, and therefore the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved (*In re Fisher*, 166 USPQ 18). The disclosure does not teach how to make and use the genus of DNAs that do encode VSCC $\alpha 2\delta$ -C subunits but are encompassed by the scope of the claims in terms of hybridization, sequence identity, or (as in claim 1) substantial sequence similarity. No working examples are taught for said DNAs, and no adequate guidance is provided by the teachings of the disclosure as to how to make this genus and what exactly such a genus could be used for if the claimed DNAs do not encode VSCC $\alpha 2\delta$ -C subunits. The specification, as filed, has no conception of isolated DNAs that hybridize to, share 70% sequence identity with, or are substantially similar to SEQ ID NO:3 but do not encode a VSCC $\alpha 2\delta$ -C subunit. In addition, the hybridization conditions must be recited in the claims as the specification teaches various and open-ended examples of what comprises high stringency hybridization conditions.

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6. Claims 1-2, 4, 6-7, 15-16, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not adequately describe DNAs that do not encode VSCC $\alpha 2\delta$ -C subunit proteins, but can hybridize to, share 70% sequence similarity to, or are substantially similar to, SEQ ID NO:3. All of the descriptions in the specification are drawn to sequences that actually encode VSCC $\alpha 2\delta$ -C subunit proteins, and not to sequences which do not encode VSCC $\alpha 2\delta$ -C subunit proteins. The claims must be limited to DNAs that actually encode VSCC $\alpha 2\delta$ -C subunit proteins (related to SEQ ID NO:3), as that is what the specification actually describes.

7. Claims 1-2, 15-16, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because the specification describes “substantially similar” as sequences with “deletions, substitutions, or additions to a DNA, RNA, or protein sequence that maintain any biologically active portion thereof of the protein product and possess any of the conserved motifs” (page 14, lines 16-18), while failing to teach sufficiently which parts of the protein products and encoding sequences are “biologically active portions” or are “conserved motifs” with sufficient clarity that the metes and bounds of the claims can be ascertained in their entirety. Since the claims encompass “any” of these active portions or conserved motifs, all such portions or motifs must be clearly taught to avoid

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vagueness in the claim language, and the specification fails to do so for all of the regions under discussion. For claim 2, the specific hybridization conditions define the metes and bounds of the claim, as the scope of the claim will vary with any changes of these conditions. Because there are multiple examples of what constitutes high stringency conditions in the specification, these conditions must be explicitly recited in the claim so that the claim is definite as to its metes and bounds.

Claim 15 is vague and indefinite because it is a method claim that does not recite clear and unambiguous process steps. It is also unclear what "a region of the DNA sequence of Claim 1, 2, or 3" actually comprises because the metes and bounds of "region" is undefined. "Amplification reaction reagents" is too generic without reference to at least a DNA primer that is some specified length of SEQ ID NO:3. As written, no primer pertaining to SEQ ID NO:3 is required!

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 15, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Harpold et al. (WO 95/04822, "Harpold"). Harpold discloses SEQ ID NOS:11 and 29-32 (pages 79-82) which are "substantially similar" to the instant invention, given that "substantially similar" encompasses "deletions, substitutions, or additions to a DNA, RNA, or protein sequence

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that maintain any biologically active portion thereof of the protein product and possess any of the conserved motifs" (page 14, lines 16-18). The Harpold products may hybridize to SEQ ID NO:3 since no hybridization conditions are recited in instant claim 2. The Harpold products are isolated (pages 86-88). Harpold teaches amplification methods (pages 27-28) that are encompassed by the broad and vague language of instant claim 15.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Harpold. Harpold discloses methods of amplification and DNA probes and primers (pages 27-28). Harpold does not explicitly disclose a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a kit employing the reagents, probes, and primers Harpold discloses in his methods for ease and convenience of having all the reagents, probes, and primers present in one convenient product to be sold for commercial use.

12. Claims 3 and 5 are in condition for allowance if the claims are amended in accordance with the election of invention to recite only SEQ ID NO:3. (All of the claims need to be amended to eliminate recitations of non-elected nucleotide sequences). Claims 3 and 5 are objected to as reciting non-elected sequences.

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13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

July 28, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
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